

**DOCKET NO.:** ISIS-5299  
**Application No.:** 10/691,012  
**Office Action Dated:** November 6, 2008

## REMARKS

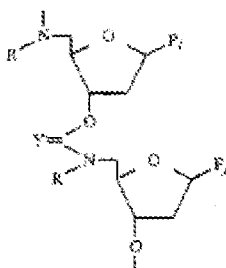
Claims 34-36, 38-41, 43-45, and 47-73 are pending in this patent application. No claims are added, amended, or canceled.

### Compliance With 35 U.S.C. § 102

Claims 34-36, 41, 48-51, 58, 59, and 65-68 were rejected as allegedly anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 5,142,047 (“the Summerton patent”). Applicants request reconsideration of this response because the Summerton patent neither discloses nor suggests any claimed invention.

For a reference to be anticipatory, it must describe “all elements of [the] claimed invention arranged as in that claim.” *Carella v. Starlight Archery*, 804 F.2d 135, 138 (Fed. Cir. 1986); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1267 (Fed. Cir. 1991). Importantly, for a rejection to be proper under 35 U.S.C. § 102, the reference must “clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *In re Arkley*, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972) (emphasis in original). Additionally, in order to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003).

The Summerton patent does not satisfy these requirements. The Office, for example, asserts that the linkages recited in the instant claims correspond to the linkage used in the following compound in the Summerton patent (Office Action at page 9).



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However, the linkage of the Summerton patent (*i.e.*, -O-C(=O)-NR- when Y is oxygen) is a urethane linkage, whereas the claims recite amide linkage (*i.e.*, -C-C(=O)-NR-). Due to the difference in the linking groups taught by the Summerton patent and those of the instant claims, no instant claim is clearly and unequivocally shown by the cited art. Thus, there is no anticipation.

In responding to our previous arguments on the subject, the November 6, 2008, Final Rejection asserts that if one ignores the oxygen atom in the -O-CO-NR- linkage, "the reference is viewed as containing the neutral amide linkage (underlined) as instantly claimed." (Final Rejection at pages 9-10). Such an interpretation, however, is not consistent with the understanding of a person skilled in the art. Such a person would not simply ignore a functional atom in analyzing the linkages, at least because whether there is an oxygen, nitrogen, or carbon atom adjacent to the CO-NR- group impacts electronic properties and is important to the nature of the group. Thus, one skilled in the art would not ignore the oxygen (and view the group as an amide) any more than one would also ignore the NR group (and view the group as a ketone).

Furthermore, a review of the Summerton patent does not support the Office's position that the oxygen atom can be ignored. The structure reproduced in the office action is found in column 5 of the Summerton patent and designated as structure "B-B". In column 6, lines 49-51, the Summerton patent refers to B-B as a carbamate-linked structure. As is well known in the art, "carbamate linkage" is another name for "urethane linkage." Thus, the cited art supports Applicants position that the B-B linkage is a urethane linkage.

Finally, Applicants submit herewith the cover page, copyright page and representative pages of "A Guide to IUPAC Nomenclature of Organic Compounds" as further support of their position. The 1993 copyright date shows that this reference was contemporary with the priority of the application. Page 126 shows representative examples of organic "amides" as recognized by IUPAC. It should be noted that each of representative amides has a carbon atom linked directly to the carbonyl. Other groups including -C(O)NR- structures are found in the pages of the submission. Lactam structures are shown on page 121. Page 176 shows certain acids that include the -C(O)NR- structure identified by the Office (*see, e.g.* carbamic acid and oxamic acid). Page 177 shows various heterocyclic compounds having the Office's cited arrangement of atoms (*see, e.g.* hydantoin, barbituric acid and alloxane). Page 179,

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section (a), lists allophanic acid, biuret, carbodiazone, carbonohydrazide, semicarbazide, carbazone, hydantoic acid, triuret and urea. These submitted pages of the IUPAC guide show over a dozen organic structures having the Office's cited -C(O)NR- group, and demonstrate that the approach employed by the IUPAC experts is consistent with Applicant's characterization of the linking groups.

For at least the foregoing reasons, Applicants submit that the cited art is not anticipatory and respectfully request that the rejection be withdrawn.

**Compliance With 35 U.S.C. §112, First Paragraph (Enablement)**

The Office Action contends that claims 34-36, 38-41, 43-45, and 47-73 lack enablement with respect to use of the recited compounds within a cell. Applicants reassert the argument presented in our last response.

Furthermore, on page 5 of the Final Rejection, the Office asserts that the "skilled practitioner would first turn to the instant specification for guidance in practicing the full scope of the claimed method" and "then turn to the prior art for such guidance." Although the Office asserts that such a practitioner would have lacked knowledge on how to produce *in vivo* effect on the intracellular nucleic acid targets by extracellular administering PNAs (Final Rejection at page 5), the Office asserts that the Summerton patent teaches *in vivo* administration of PNAs (Final Rejection at pages 7-9). Thus, in this passage the Office appears to indicate that the Summerton patent would have enabled *in vivo* application of PNAs.

For at least these reasons, Applicant's submit that invention is indeed enabled. Withdrawal of the rejection is respectfully requested.

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**Conclusions**

Applicants believe the foregoing constitutes a complete response to the Office Action and submit that all pending claims are in condition for ready allowance. An early Office Action to that effect is, therefore, earnestly solicited.

Respectfully submitted,

Date: December 22, 2008

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